Mecklenburg County Public Health
COVID-19 Vaccine FAQ – Healthcare Providers

How is vaccine distributed to enrolled providers for administration to patients?

Location and quantity of vaccine shipments in the county are determined by North Carolina Department of Health and Human Services (NC DHHS), **not** by MCPH at this time.

- As information becomes available from NC DHHS, we will provide updates regarding:
    - When additional enrolled providers will receive vaccine soon; we will share information as it becomes available.
    - Provider enrollment opportunities for healthcare practices that have not yet enrolled.
- Long-term care facilities (LTCFs) will primarily receive COVID vaccine through the Pharmacy Partnership for Long-Term Care Program.
    - MCPH will support LTCFs to identify and address gaps in vaccination coverage and provide vaccine-related guidance

How will providers that are not affiliated with a hospital network receive the vaccine?

At this time, initial shipments of the COVID-19 vaccine in NC will go to hospital systems followed by local health departments to follow the prioritization guidelines set forth by the state. Location and quantity of vaccine shipments in this county are currently determined by NC DHHS, **not** by MCPH.

- Other healthcare providers that were enrolled as vaccine providers will get shipments of the vaccine eventually, as availability increases in the coming months.
- Independent providers that are not affiliated with hospital networks who would like to receive vaccine shipments in the future are encouraged to complete the vaccine provider enrollment agreement (details on how to complete can be found in the Vaccine Provider Outreach and Enrollment section below).

Healthcare personnel at non-hospital affiliated facilities who **meet the Group 1 eligibility criteria to receive vaccine** will receive additional communication from MCPH regarding vaccine availability for their eligible healthcare staff as vaccine supply increases i**n accordance with the state and county prioritization plans**.

Sign Up Here to receive health advisories via email and/or fax. Click here to view previous advisories for healthcare providers.

What is the process for health care or other facilities to submit information to MCPH for enrollment in the COVID Vaccine Management System (CVMS)?

MCPH currently has a limited number of appointments available and will work to add additional appointment options based on vaccine supply. If there are no appointments available, please continue to check StarMed.care for openings and/or the MCPH vaccine page for updates. Please reach out to MeckCVMS@mecknc.gov with questions.

Healthcare workers **may also schedule an appointment through Atrium's COVID vaccine website,** even if they are not affiliated with the hospital.

Local Health Department's Role in Prioritization and Delivery

What is the LHD's Role in regards to the COVID-19 vaccine?

Mecklenburg County is working closely with our hospitals, emergency management and community providers to develop a coordinated approach to COVID-19 vaccine communication, outreach and delivery in Mecklenburg County through:

- Consistent messaging regarding vaccine safety, prioritization, and delivery.
- **Equitable vaccine delivery to prioritized individuals and populations.**
- Transparent sharing of data regarding vaccine administration and recipients (including demographic data).

When the COVID-19 vaccine is available, will it ship directly to the facilities approved for vaccinations? Or will it all come to the LHD for distribution?

Vaccine will initially be shipped to hospitals and local health departments.

- Enrolled providers will receive shipments from NC DHHS directly to their facilities. Those that do not receive an allocation from NC DHHS or have the capacity to receive more doses, can reach out to MCPH for a transfer of vaccines. MCPH will transfer vaccines to enrolled providers if there is an excess available.
- If a provider is enrolled in the COVID-19 vaccination program and can administer the minimum ship quantity (100 doses in most cases, but 1,000 doses for at least 1 vaccine) they can receive shipments directly to their site.
    - LHDs may need to provide vaccine doses (if permitted by CDC) to places within their county that do not meet the minimum ship to quantities. Additional information will be provided as it becomes available.

How will the vaccine be distributed?

- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction (State) immunization programs.

- Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.
- COVID-19 vaccination providers will be required to report administration within 24 hours of the administration and ongoing COVID-19 vaccine inventory at least daily. Vaccine orders will be approved and transmitted by the state in CDC's Vaccine Tracking System (VTrckS) for vaccination providers.

Will ancillary supplies be shipped with the amount of vaccine or will we need to request that separately?

Ancillary supply kits will come with the vaccine and will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.

COVID-19 Vaccine Management System (CVMS)

What system will be used for COVID-19 vaccine administration data collection?

Initially, NC DHHS will not be using NCIR for COVID vaccine administration data collection. Based on CDC requirements for data entry, the increased user volume, system capacity issues, and the need for vendor managed adjustments, NCIR is not the most suitable data system.

- North Carolina will use a new system, the COVID-19 Vaccine Management System (CVMS) that will be web based and provided to all COVID-19 enrolled providers at no charge. The new system is being built to meet COVID-19 data element and time collection requirements, will have English and Spanish options with additional considerations in later releases, support 2d barcoding, be cloud based, support unlimited users, and be customizable to NC.
- Provider sites can have multiple systems users and will receive additional access information when the system is available. The initial release will not support connection with EHRs, but that is functionality we have as a goal for a later release.

What types of identifying data will be required in the COVID Vaccine Management System (CVMS)?

Identifying data will include recipients first and last name, date of birth, address, and sex.

Vaccine Provider Enrollment

Who can enroll as a COVID-19 vaccine provider through the NC COVID Vaccine Management System?

Who can enroll in the COVID-19 Vaccine Management System (CVMS):

- Eligible health care providers who are interested in administering the COVID-19 vaccine and can self-register in the CVMS Provider Enrollment Portal.

Before getting started in CVMS, a representative from your organization should:

- Attend a live CVMS Provider Enrollment Training Session.
- Review and complete the COVID-19 Vaccine Readiness Checklist.
- Identify a single point of contact for your employees to send questions or provide feedback related to the administration of COVID-19 vaccines (Knowledge Base).

Enrollment can be initiated at http://covid.enroll.ncdhhs.gov. Enrolled COVID-19 vaccine providers must be credentialed/licensed in North Carolina.

Please understand that while currently qualified providers are welcome to enroll, requests will be addressed in an order aligned with the Prioritization Phases and the timeline for approval will vary. The state will continuously reassess enrollment prioritization based on needs.

You can find more information on enrolling in the state CVMS system by visiting:

COVID-19 Vaccine Management System (CVMS): NC DHHS COVID-19

End-to-end Provider Enrollment Process (nc.gov)

Pharmacy Partnership for Long-term Care Program

Will the Local Health Department (LHD) be involved at any level with distribution of the vaccine to Long Term Care Facilities (LTCF) given the proposed partnership?

The CDC is partnering with CVS and Walgreens pharmacies to offer on-site COVID-19 vaccination service for LTCFs.

NOTE: **the time for LTCFs to enroll in the federal partnership program has passed.** If you are a representative for a LTCF that has not received the COVID-19 vaccine through the federal partnership program, you can email MeckCVMS@MecklenburgCountyNC.Gov to request assistance from MCPH.

- The majority of LTCFs in Mecklenburg County have participated in the Federal Partnership Program.

- MCPH will continue to support LTCFs to identify and address gaps in vaccination coverage and provide vaccine-related guidance

How will COVID-19 vaccine be allocated for distribution to pharmacies?

Through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination's second phase of vaccine rollout, select pharmacy partners will directly order and receive allocation of COVID-19 vaccine from the federal government.

- The federal allocation to pharmacies will not cover every pharmacy in the United States.
    - Pharmacies not included in the federal allocation program are still encouraged to be part of the vaccination program and should coordinate with their jurisdictions to become COVID-19 vaccination providers.
- N.C. is working to determine what pharmacies will be a part of the federal partnership and will target those that are not.

Payment

Will there be a cost to the public for the vaccine?

The goal of the federal government is for there to be no upfront costs to providers and no out-of-pocket cost to the vaccine recipient.

- Various plans, supported by the CARES Act and the Families First Coronavirus Response Act, are under development with the objective of ensuring no one will be charged any out–of pocket expenses for the administration of the vaccine either. The objective is to ensure no one desiring vaccination will face an economic barrier to receiving one. Section 3203 of the CARES Act
- (P.L. 116-136) requires health insurance issuers and plans to cover any ACIP-recommended COVID-19 preventive service, including vaccines, without cost sharing within 15 days of such recommendation to the CDC.
- Through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination, select pharmacy partners will receive a direct allocation of COVID-19 vaccine. This program will provide critical vaccination services for the U.S. population with vaccine administered at retail locations at no cost to recipients.

Currently Authorized COVID-19 Vaccines – Clinical Considerations

mRNA Clinical Considerations (Pfizer/Moderna) | CDC
CDC Presentation (Janssen) | CDC

Product Overviews and EUA Information

Pfizer-BioNTech and Moderna

- Mechanism of Action: Lipid nanoparticle-formulated mRNA vaccine encoding the SARS-CoV-2 spike protein
  - Spike protein is presented on the surface of cells to be detected by antibodies, triggering an immune response.
- Pfizer-BioNTech: Emergency Use Authorization granted on December 13, 2020
  - Authorized for use in persons aged ≥16 years.
- Moderna: Emergency Use Authorization granted on December 18, 2020
  - Authorized for use in persons aged ≥18 years.

Janssen (Johnson & Johnson)

- Mechanism of action: Viral vector – using a non-replicating human adenovirus – encoding the SARS-CoV-2 spike protein.
  - Adenovirus enters cell to deliver spike protein. Vector components are broken-down via lysis after delivery.
  - Spike protein is presented on the surface of cells to be detected by antibodies, triggering an immune response.

- Janssen (Johnson & Johnson): Emergency Use Authorization granted on February 27, 2021
  - Authorized for use in persons aged ≥18 years.

Administration

Pfizer BioNTech and Moderna

- 2-dose series administered intramuscularly 21 days apart (Pfizer-BioNTech) or 28 days apart (Moderna)
- **Both doses are necessary for protection;** efficacy of a single dose has not been systematically evaluated
- It is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose.
  - There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window.
  - If the second dose is administered beyond these intervals, there is no need to restart the series.

Johnson & Johnson

- Single-dose series administered intramuscularly

Interchangeability

All currently authorized COVID-19 vaccines are **not interchangeable** with one another

- Safety and efficacy of a mixed series has not been evaluated
- Persons initiating series with Pfizer-BioNTech COVID-19 or Moderna vaccine should complete series with same product
- If two doses of different mRNA COVID-19 vaccine products inadvertently administered, no additional doses of either vaccine recommended at this time
    - Recommendations may be updated as further information becomes available or additional vaccine types authorized

Use of the Johnson & Johnson Vaccine to Complete an Unfinished Series

- If a first dose of an mRNA COVID-19 vaccine was received but the patient was unable to complete series with the same mRNA vaccine:
    - Single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose
    - Considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series (mRNA/viral vector)

Coadministration with other vaccines

COVID-19 vaccines should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines

- Due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines
- If COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine
- A shorter interval may be used in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks (e.g., tetanus toxoid vaccine for wound management, etc.) or to avoid barriers or delays to vaccination.

Persons with a history of SARS-CoV-2 Infection

Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection

- Data from phase 2/3 clinical trials suggest vaccination safe and likely efficacious in these persons

- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making

Persons with known *current* SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) and criteria have been met to discontinue isolation
- No minimal interval between infection and vaccination
- However, current evidence suggests reinfection uncommon in the 90 days after initial infection and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.

Persons who previously received passive antibody therapy for COVID-19

- Currently, no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
- Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses
    - Based on estimated half-life of therapies and evidence suggesting reinfection is uncommon within 90 days of initial infection

Persons with a *known* SARS-CoV-2 exposure

Community or outpatient setting:

- Defer vaccination until quarantine period has ended to avoid exposing healthcare personnel (HCP) or other persons during vaccination visit

Residents of congregate healthcare settings (e.g., long-term care facilities):

- May be vaccinated, as likely would not result in additional exposures. HCP are already in close contact with residents and should employ appropriate infection prevention and control procedures

Residents of other congregate settings (e.g., correctional facilities, homeless shelters)

- May be vaccinated, in order to avoid delays and missed opportunities for vaccination – Where feasible, precautions should be taken to limit mixing of these individuals with other residents or non-essential staff

Persons with underlying medical conditions

All currently authorized COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination.

- Phase 2/3 clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

Immunocompromised persons

Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19.

- Data not currently available to establish safety and efficacy of vaccine in these groups
- These individuals may still receive any of the currently authorized COVID-19 vaccines unless otherwise contraindicated
- Individuals should be counseled about:
    - Unknown vaccine safety and efficacy profiles in immunocompromised persons
    - Potential for reduced immune responses
    - Need to continue to follow all current guidance to protect themselves against COVID-19

Pregnant women and COVID-19 Vaccines

There are no data on the safety of COVID-19 vaccines in pregnant women.

Clinical trials to evaluate safety and efficacy of COVID-19 vaccines in pregnant people planned or underway.

- No concerns demonstrated in animal developmental and reproductive toxicity (DART) studies for all currently authorized COVID-19 vaccines
- mRNA vaccines and pregnancy
    - Currently authorized COVID-19 vaccines are all inactivated vaccines
    - They are degraded quickly by normal cellular processes and don't enter the nucleus of the cell
- COVID-19 and pregnancy
    - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
    - Might be an increased risk of adverse pregnancy outcomes, such as preterm birth

If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision, but is not required.

Considerations for pregnant women

- Considerations for vaccination in pregnant women:
    - Level of COVID-19 community transmission, (risk of acquisition)
    - Personal risk of contracting COVID-19, (by occupation or other activities)
    - Risks of COVID-19 to her and potential risks to the fetus
    - Efficacy of the vaccine
    - Known side effects of the vaccine
    - Limited data about the vaccine during pregnancy
- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes
- Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is **not recommended.**

Breastfeeding / Lactating women

- There are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion
- mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant
- **If a lactating woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated**

Patient Vaccine Counseling

Side Effects / Reactogenicity

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination side effects
- For 2-dose vaccine series: unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19.
- Antipyretic or analgesic medications may be taken for treatment of postvaccination symptoms
    - Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time, due to lack of information on impact of use on vaccine-induced antibody responses.

Vaccine Efficacy

Pfizer and Moderna

Two doses required to achieve optimal efficacy

- Patients should be counseled on importance of completing the 2-dose series in order to optimize protection

- Full protection is considered to start at 14 days following second dose in series.
- The FDA has not evaluated efficacy of a partially completed series for either vaccine

Johnson and Johnson

- Single-dose series
- Full protection is considered to start at 14 days following dose.

It is important to inform patients that even though currently authorized COVID-19 vaccines differ in efficacy of preventing COVID-19 infection, all vaccines:

- Have >89% efficacy against hospitalizations from COVID-19
- Have 100% efficacy against deaths from COVID-19

Public health recommendations for vaccinated persons

- Protection from vaccine is not immediate
    - For Pfizer/Moderna, full protection requires both doses in series
    - For all currently authorized vaccines, full protection begins 14 days following series completion
- No vaccine is 100% effective
- Given the currently limited information on how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts, vaccinated persons should continue to follow all current guidance to protect themselves and others, including:
    - Wearing a mask
    - Staying at least 6 feet away from others
    - Avoiding crowds
    - Washing hands often
    - Following CDC travel guidance
    - Following any applicable workplace or school guidance

Contraindications and Precautions

Contraindications

- Severe allergic reaction (e.g., anaphylaxis) **after a previous dose** or **to any component of the specific vaccine** the individual is receiving.
- Immediate allergic reaction of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine.

Precautions

- Severe allergic reaction to **any** vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous).
    - Actions:
        - Risk assessment
        - Potential deferral of vaccination
        - 30 min observation period if vaccinated

For All Patients

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.
    - Vaccine providers should observe all patients after vaccination to monitor for the occurrence of immediate adverse reactions:
        - Persons with a history of anaphylaxis (due to any cause): 30 minutes
        - All other persons: 15 min

Contraindications and precautions for COVID-19 vaccines

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	Among persons without a contraindication, a history of: • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Among persons without a contraindication or precaution, a history of: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies Actions: • 30-minute observation period: persons with history of anaphylaxis (due to any cause) • 15-minute observation period: all other persons

Differing Contraindications and Precautions Related to the Janssen (Johnson and Johnson) Vaccine

- **Polyethylene glycol (PEG)** is an ingredient in both mRNA COVID-19 vaccines currently authorized, and **polysorbate 80** is an ingredient in the Janssen COVID-19 vaccine.

- PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur.
- Persons with a **contraindication** to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a **precaution** to Janssen COVID-19 vaccine.
- Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose).
- Persons with a **contraindication** to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a **precaution** to mRNA COVID-19 vaccines.
- In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

Interpretation of SARS-CoV-2 test in vaccinated person

Viral tests: Prior receipt of currently approved mRNA vaccines will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests

Antibody tests:

- Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to spike or nucleocapsid proteins
- Currently approved mRNA vaccines contain mRNA that encodes the spike protein; thus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination
    - To evaluate for evidence of prior infection in an individual with a history of an mRNA COVID-19 vaccination, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used.

How will vaccination history impact isolation and quarantine guidance?

Vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are <u>not</u> required to quarantine if they meet all of the following criteria:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
- Experience the COVID-19 exposure within 3 months following receipt of the last dose in the vaccine series
- Have remained asymptomatic since the current COVID-19 exposure

Persons who do not meet all 3 of the above criteria should continue to follow current quarantine guidance after exposure to someone with suspected or confirmed COVID-19.

Source: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines | CDC

Are vaccine providers required to report adverse events?

Adverse events that occur in a recipient after receipt of COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS).

- FDA **requires** that vaccination providers report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under EUA.
    - Reporting is encouraged for any clinically significant adverse event, whether it is clear that a vaccine caused the adverse event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.htmlexternal icon or 1-800-822-7967.
- In addition, CDC has developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. The CDC/v-safe call center follows up on reports to v-safe that indicate a medically significant health impact to collect additional information for completion of a VAERS report. Information on v-safe is available at https://www.cdc.gov/vsafe.